K113496

Coloplast

FEB 1 4 2012

3 510(K) SUMMARY

510(k) Owner/Submitter	Coloplast A/S; Division: Coloplast Corp Holtedam 1 Humlebaek 3050 - Denmark
Contact	Janell A. Colley Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA
Date Prepared	30 June 2011
Common name/ Classification	Virtue: Surgical Mesh: 21CFR 878.3300; Alexis: Surgical drape and drape accessories: 878.4370
Proprietary Name	Virtue Male Sling System with Alexis Wound Retractor
Predicate Devices	Virtue: K101297 Alexis: K041711

Device Description

The Coloplast Virtue Male Sling System consists of a polypropylene mesh with four arms. The four arms are each covered with a sleeve and a suture is affixed at each end to allow for attachment to the introducer. The introducer consists of a handle and stainless steel wireform. The device kit (implant plus introducer) is provided sterile and for single use only.

The Alexis Wound Retractor is constructed as a cylindrical membrane sheath that has two rings attached to each open end. The rings are molded in a plastic material. The wound Retractor package includes an incision template. The device is manufactured in four sizes, small, medium, medium-large, and large.

The Coloplast Virtue Male Sling System with Alexis Wound Retractor consists of one Virtue Sling System and one small Alexis Wound Retractor, provided in a single shelf box.

Intended Use

The Virtue Male Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

The Applied Alexis Wound Retractor is indicated for use to:
Access the abdominal cavity during surgery through an atraumatically retracted incision.
Deliver maximum exposure of the abdominal cavity with minimum incision.
Protect against wound contamination during laparoscopic and open surgery.
The smaller two sizes of Alexis are also intended to be used to:
Seal off the incision opening to permit insufflating the peritoneum.
Convert the incision wound to an additional trocar port site.
Access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures through an atraumatically-retracted incision.

Technological Characteristics Compared to Predicate

The Virtue Male Sling System with Alexis Wound Retractor has the same intended use, design, materials and fundamental scientific technology as the predicates Virtue System K101297 and Alexis K041711.

Summary Of The Nonclinical Tests Submitted

The minor design modifications, including a decrease in the mesh body and addition of suture knots were evaluated via design verification testing and simulated use tests in a cadaveric laboratory. These tests confirmed that the Virtue System as modified meets the established design specifications and is substantially equivalent to the predicate. The Virtue System was subjected to biocompatibility testing to support the original 510k (K041711), and since there have been no changes to materials, the previous testing supports the modified Virtue device. In addition, since there were no changes to the sterilization method, SAL, or sterilization parameters, the existing sterilization validation supports the modified Virtue device.

Summary Of Clinical Tests Submitted (As Applicable)

Not applicable

Conclusions Drawn From The Nonclinical Tests

The Virtue Male Sling System with Alexis Wound Retractor is substantially equivalent to the predicates.

DSORD cleared surgical mesh indicated for pelvic organ prolapse and stress urinary incontinence (male and female) under 21 CFR 878.3300 (surgical mesh) and product codes FTL (surgical mesh, synthetic) and FTM (surgical mesh). DRGUD is correcting the substantially equivalent letters for these devices to reflect the new product codes. At this time, the regulation number for these devices remains the same.

Cheryl R. Mackey, Program Analyst, DRGUD — Date: 9/28/12

John H. Baxley, Biomedical Engineer, ULDB — Date: 9/28/2012

Glenn B. Bell, Branch Chief, ULDB — Date: 28 Sept 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Janell A. Colley
Regulatory Affairs Manager
Coloplast A/S
1601 West River Road North
MINNEAPOLIS MN 55411

OCT 12 2012

Re: K113496
Trade/Device Name: Virtue Male Sling System with Alexis Wound Retractor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTM, GAD
Dated: January 18, 2012
Received: January 20, 2012

Dear Ms. Colley:

This letter corrects our substantially equivalent letter of February 14, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 STATEMENT OF INDICATIONS FOR USE

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The smaller two sizes of Alexis are also intended to be used to:

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Convert the incision wound to an additional trocar port site.
Access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures through an atraumatically-retracted incision.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113496